DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 2, 2015

CORETESTS, INC.
WEN LI
REGULATORY AFFAIRS SPECIALIST
6190 YARROW DRIVE
CARLSBAD CA 92011

Re: K150063
Trade/Device Name: ACCU NEWS One Step hCG Pregnancy Test Strip
ACCU NEWS One Step hCG Pregnancy Test Cassette
ACCU NEWS One Step hCG Pregnancy Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX
Dated: August 14, 2015
Received: August 17, 2015

Dear Wen Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150063

Device Name
ACCU NEWS One Step hCG Pregnancy Test Strip
ACCU NEWS One Step hCG Pregnancy Test Cassette
ACCU NEWS One Step hCG Pregnancy Test Midstream

Indications for Use *(Describe)*

ACCU NEWS One Step Pregnancy Test Strip: The ACCU NEWS One Step Pregnancy Test Strip is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

ACCU NEWS One Step Pregnancy Test Cassette: The ACCU NEWS One Step Pregnancy Test Cassette is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

ACCU NEWS One Step Pregnancy Test Midstream: The ACCU NEWS One Step Pregnancy Test Midstream is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary

A. Submitter Information

Coretests Inc.
6190 Yarrow Drive, Carlsbad, CA 92011, USA.
Phone Number: 858-333-1122
Contact Person: Wen Li
Summary Prepared on September 29th, 2015

B. Trade Name, common name, classification name

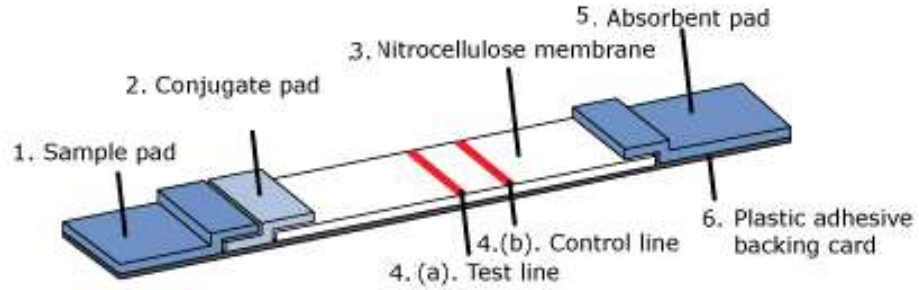
Trade Names: ACCU NEWS™ One Step hCG Pregnancy Test Strip, ACCU NEWS™ One Step hCG Pregnancy Test Cassette, and ACCU NEWS™ One Step hCG Pregnancy Test Midstream.
Common Name: Qualitative Lateral Flow Immunoassay
Classification: Class II
Regulation Number: 21 CFR 862.1155 Human chorionic gonadotropin test system
Product code: LCX
Panel: Clinical Chemistry (75)

C. Predicate device

K043443 Wondfo One Step HCG Urine Pregnancy Test

D. Device description

ACCU NEWS™ One Step hCG Pregnancy Test is a qualitative lateral flow test for the detection of hCG (human chorionic gonadotropin) hormone, which is present in urine during the early stage of pregnancy. It is built on a basic lateral flow immunoassay test strip model containing 6 components as illustrated below:



The nitrocellulose membrane is coated with Goat anti-mouse IgG polyclonal antibody on the control line and anti-alpha hCG mouse monoclonal antibody on the test line. The conjugate pad contains colloidal-gold-labeled anti-beta mouse monoclonal hCG antibody. When urine specimen is drawn through the sample pad, the hCG present in the urine will react with the anti-beta monoclonal hCG antibody on the conjugate pad and the anti-alpha monoclonal hCG antibody on the test line to develop visible lines in the test region.

Test Result Interpretation:
Not Pregnant: No visible pink line appearing in the test region.
Pregnant: A visible pink line appearing in the test region.
Invalid: No visible line in control region, regardless if there is a visible line in the test region or not.

The ACCU NEWS™ One Step hCG Pregnancy Test is available in three different formats: 1) strip, 2) cassette, and 3) midstream.

Strip Format

The Strip format is a test strip used by itself without any housing components. Urine specimen is collected in a cup and the sample pad is dipped into the urine directly.

Cassette Format

The Cassette format includes a test strip housed in a plastic cassette. Urine specimen is collected in a cup and a dropper is provided to transfer the urine specimen to the sample well of the cassette, wetting the sample pad to activate the test.

Midstream Format

The Midstream format includes a test strip housed in a plastic case with an absorbent tip contacting the sample pad of the test strip. When the absorbent tip is placed in a urine steam it draws urine specimen onto the sample pad of the test strip to activate the test.

All three formats are built on the basic test strip model containing 6 components as illustrated above. The strips used in the three different formats contains the same components except that the plastic adhesive backing card, absorbent pad and sample pad are in different sizes. This is specified in the table below:

Component	Strip	Cassette	Midstream
Plastic Adhesive Backing Card	300 x 80 mm	300 x 60 mm	300 x 85 mm
Absorbent pad	298×33 mm	298×23 mm	298×31mm
Sample Pad	300 x 24 mm	300 x 20 mm	300 x 40 mm

E. Intended use

ACCU NEWS™ One Step Pregnancy Test Strip: The ACCU NEWS™ One Step Pregnancy Test Strip is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

ACCU NEWS™ One Step Pregnancy Test Cassette: The ACCU NEWS™ One Step Pregnancy Test Cassette is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

ACCU NEWS™ One Step Pregnancy Test Midstream: The ACCU NEWS™ One Step

Pregnancy Test Midstream is a lateral flow immunoassay to qualitatively detect the presence of human Chorionic Gonadotropin (hCG) hormone in urine specimen to aid early detection of pregnancy for both prescription use and OTC use.

F. Summary of the technological characteristics of your device compared to the predicate device

Similarities		
Feature	***Subject Device***	***Predicate Device***
Intended Use	It is intended for both professional and over-the-counter use for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.	It is intended for both professional and over-the-counter use for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.
Specimen Type	Urine	Urine
Technology	Lateral Flow Immunoassay	Lateral Flow Immunoassay
Basic Components	Test strip containing nitrocellulose membrane, sample pad, alpha and beta hCG antibodies	Test strip containing nitrocellulose membrane, sample pad, alpha and beta hCG antibodies
Detection Limit	25 mIU/mL	25 mIU/mL
Storage Temperature	4-30ºC	4-30ºC
Formats	Strip, Cassette, Midstream	Strip, Cassette, Midstream
Traceability	WHO 3rd International Standard	WHO 3rd International Standard
Differences		
Feature	***Subject Device***	***Predicate Device***
Read Time	at 5 minutes	3-5 minutes
High Dosage Hook Effect	No high dosage hook effect for hCG up to 500,000 mIU/mL	No high dosage hook effect for hCG up to 100,000 mIU/mL
Specificity	LH at 1000mIU/mL, FSH at 1000mIU/mL, and TSH at 1000µIU/mL	LH at 300mIU/mL, FSH at 300 mIU/mL, and TSH at 1000 mIU/mL
pH Interference	No interference for urine with pH 2-9	No interference for urine with pH 4-9
Specific Gravity Interference	No interference for urine with Specific Gravity 1.003-1.030	No interference for urine with Specific Gravity 1.000-1.050

G. Non-clinical performance data

a. Read Time Window

To determine the optimal time to interpret the test results of the ACCU NEWS™ One Step hCG Pregnancy Test, 10 devices from each format (Strip, Cassette, and Midstream) were tested with each of the urine samples containing 0, 12.5, 18.75, 25, 50, and 100mIU/mL hCG. Data indicated that test result was most accurate when it

was interpreted at 5 minutes.

b. Precision/Sensitivity

1. Three lots of devices for each format were used to test blind-labelled urine samples containing 0, 12.5, 18.75, 25, 50, and 100mIU/mL of hCG. All urine samples were calibrated against the hCG standard WHO 3rd IS. The study was carried out at three sites (one internal site and two external sites representative of the intended use setting). Each site tested a unique lot of test device. For each format, at least 30 urine samples were tested for each concentration.

Table 1: Precision Study Data for Strip

hCG conc. (mIU/mL)	Lot #1		Lot #2		Lot #3		Total	
	+	-	+	-	+	-	+	-
0	0	10	0	10	0	10	0	30
12.5	0	10	0	10	0	10	0	30
18.75	0	10	0	10	0	10	0	30
25	10	0	10	0	10	0	30	0
50	10	0	10	0	10	0	30	0
100	10	0	10	0	10	0	30	0

Table 2: Precision Study Data for Cassette

hCG conc. (mIU/mL)	Lot #1		Lot #2		Lot #3		Total	
	+	-	+	-	+	-	+	-
0	0	10	0	10	0	10	0	30
12.5	0	10	0	10	0	10	0	30
18.75	0	10	0	10	0	10	0	30
25	10	0	10	0	10	0	30	0
50	10	0	10	0	10	0	30	0
100	10	0	10	0	10	0	30	0

Table 3: Precision Study Data for Midstream

hCG conc. (mIU/mL)	Lot #1		Lot #2		Lot #3		Total	
	+	-	+	-	+	-	+	-
0	0	10	0	10	0	10	0	30
12.5	0	10	0	10	0	10	0	30
18.75	0	10	0	10	0	10	0	30
25	10	0	10	0	39	1	59	1
50	10	0	10	0	10	0	30	0
100	10	0	10	0	10	0	30	0

Test result demonstrated that all three formats of ACCU NEWS™ One Step hCG Pregnancy Test were able to produce consistent and precise test results.

2. Linearity/Assay reportable range:
   Not applicable. This is a qualitative test.

3. Detection Limit:
   The Precision/Sensitivity study demonstrated that the detection limit for the test was 25 mIU/mL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods)

The test is calibrated against reference material traceable to WHO International Standard 3rd edition.

A shelf-life stability test of the device was performed in accelerated temperature at 60°C. The results support that the device was stable for 2 years when stored at 4-30°C.

d. Comparison Study

Urine samples were randomly collected from 250 female donors from three sites at various times throughout the day. About 50% of the donors were suspected to be pregnant. Donor age range was from 18 to 43. Healthcare professionals tested each urine sample with each format of ACCU NEWS™ One Step hCG Pregnancy Test and a predicate hCG test. Test results were compared.

Table 4: Data Summary for Comparison Study

		ACCU NEWS™ One Step hCG Pregnancy Test					
		Midstream		**Cassette**		**Strips**	
		Positive	**Negative**	**Positive**	**Negative**	**Positive**	**Negative**
Predicate Device Result	**Positive**	124	0	124	0	124	0
	Negative	0	126	0	126	0	126
	Total	124	126	124	126	124	126
	% Agreement	100%		100%		100%	

Test result demonstrated that test results from all three formats of the ACCU NEWS™ One Step hCG Pregnancy Test had 100% agreement with that of the predicate device.

e. Specificity

Specificity was determined by testing the ACCU NEWS™ One Step hCG Test with structurally related compounds spiked in negative urine samples and positive (hCG 25 mIU/mL) urine samples. The compounds analyzed were luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid stimulating hormone (TSH). Five tests were performed for each compound. Result demonstrated that ACCU NEWS™ One Step hCG Test was not interfered by FSH, TSH, and LH at the levels of 1000mIU/mL, 1000µIU/mL, and 1000mIU/mL respectively. However, LH, FSH, and TSH may cause false negative readings at concentrations of >1000 mIU/mL, >1000 mIU/mL, and >1000 µIU/mL respectively.

f. Interference

1. Exogenous Compounds

To determine if some exogenous compounds would react and interfere with the ACCU NEWS™ One Step hCG Pregnancy Test, positive urine samples (hCG 25 mIU/mL) and negative urine samples were spiked with individual chemicals to specific concentrations. Each spiked urine sample was tested with five ACCU NEWS™ One Step hCG Pregnancy Test devices from each format. Results showed that ACCU NEWS™ One Step hCG Pregnancy Test was not interfered

by the substances listed below at their specific concentrations.

Substance	Concentration
(1R,2S)-(-)-Ephedrine	20 mg/dL
(1S,2R)-(+)-Ephedrine	20 mg/dL
Acetylsalicylate Acid	20 mg/dL
Albumin (Human)	2000 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Acetaminophen	20 mg/dL
Ampicillin	5.3 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Gentisic Acid	20 mg/dL

Substance	Concentration
Glucose	2000 mg/dL
Hemoglobin	250 mg/dL
Ibuprofen	40 mg/dL
Methadone	10 mg/dL
Morphine	10 mg/dL
Nicotine	20 mg/dL
Tetracycline	1.5 mg/dL
Acetone	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic acid	20 mg/dL
Uric Acid	20 mg/dL
DL-β-Hydroxybutyric Acid	2000 mg/dL

2. pH Study

To determine if different pH values in urine would have an effect on the ACCU NEWS™ One Step hCG Pregnancy Test, positive (hCG 25 mIU/mL) and negative urine samples with the following pH values: 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0 were tested. Each urine sample was tested with three test devices from each format of the ACCU NEWS™ One Step hCG Test. Result showed that pH values 2.0-9.0 in urine did not interfere with the performance of the test.

3. Specific Gravity

To determine if different specific gravity values in urine can affect the ACCU NEWS™ One Step hCG Pregnancy Test, positive (25 mIU/mL) and negative hCG urine samples with the following specific gravity levels: 1.003, 1.005, 1.010, 1.015, 1.020, and 1.030 were tested. Each urine sample was tested with three test devices from each format of the ACCU NEWS™ One Step hCG Pregnancy Test. Result showed that the test functioned properly with no interference from these various specific gravity values in urine.

4. High Dose/Hook Effect

To determine if high concentrations of hCG would cause false negative result on the ACCU NEWS™ One Step hCG Pregnancy Test. Urine samples spiked with 50, 100, 200, 300, and 500 IU/mL of hCG were tested with the device. Each urine sample was tested with three test devices from each format of the ACCU NEWS™ One Step hCG Pregnancy Tes. Result showed that the device did not exhibit high dose/hook effect for urine containing up to 500 IU/mL (or 500,000 mIU/mL) of hCG.

5. hCG β-core fragment

To determine the effects of β-core hCG fragment on the ACCU NEWS™ One Step hCG Test, the device was tested with negative and positive (hCG 25mIU/mL) hCG urine samples spiked with β-core hCG fragment at the concentrations of 20,000 pmol/L, 25,000 pmol/L, 50,000 pmol/L, 62,500 pmol/L, 100,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L, 500,000 pmol/L

and 1000,000 pmol/L. Result showed that β-core hCG fragments did not interfere with the test result of the device at or below the concentration of 100,000pmol/L. However, at a concentration of >100,000 pmol/L, hCG β-core Fragment may cause false negative reading.

H. Clinical performance data

a. Clinical Sensitivity:

Not Applicable

b. Clinical Specificity:

Not Applicable

c. Other Clinical Supportive Data:

OTC lay-user Test Result

Urine samples were randomly collected from 250 female donors at three sites. About 50% of the donors were suspected to be pregnant. Donor age range was from 18 to 43. Donors were given all three formats of the ACCU NEWS™ One Step hCG Pregnancy Test to test the collected urine samples. The same urine samples were tested by healthcare professionals using the ACCU NEWS™ One Step hCG Pregnancy Test. The recorded test results from the lay users were compared with that from the healthcare professionals.

Table 5: Data Summary of OTC Lay-User Test Result for Strip

		ACCU NEWS™ One Step hCG Pregnancy Test Strip	
		Positive	**Negative**
Professional Test Result (Strip Format)	**Positive**	124	0
	Negative	0	126
	Total	124	126
	% Agreement	100%	

Table 6: Data Summary of OTC Lay-User Test Result for Cassette

		ACCU NEWS™ Step hCG Pregnancy Test Cassette	
		Positive	**Negative**
Professional Test Result (Cassette Format)	**Positive**	124	0
	Negative	0	126
	Total	124	126
	% Agreement	100%	

Table 7: Data Summary of OTC Lay-User Test Result for Midstream

		ACCU NEWS™ One Step hCG Pregnancy Test Midstream	
		Positive	**Negative**
Professional Test Result (Midstream Format)	**Positive**	124	0
	Negative	0	126
	Total	124	126
	% Agreement	100%	

Data showed 100% agreement between lay user results and professional result. This demonstrated that the device was easy enough to be used by untrained lay users. In addition, each participant was given an English questionnaire to assess the readability of the labeling. The result showed that lay users found the product instruction to be easy to understand and the device to be easy to use.

I. Conclusion

The performance characteristics studies performed demonstrated substantial equivalency between ACCU NEWS^{TM} One Step hCG Pregnancy Test and the predicate device.